UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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WILLIAM J. MARTINI
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LETTER OPINION

May 21, 2007

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Re: In re: Human Tissue Products Liability Litigation
Civil Action No. 2:06-00135 (WJM); MDL No. 1763

Dear Counsel:

On August 16, 2006, Plaintiffs filed a motion requesting that Defendants give prompt and urgent notice to unnamed class members of the need to have a blood test. On September 11, 2006, Magistrate Judge Ronald J. Hedges adjourned this motion until further order of the Court. However, at oral argument on Defendants' "Science First" motion on April 11, 2007, Plaintiffs reiterated their request for notice to unnamed class members and later re-submitted to the Court their previously-filed motion. Defendants then supplemented the record by providing the Court with a similar motion filed by Plaintiffs in *Sunderman v. Regeneration Technologies, Inc., et al.*, Case No. 1:06-CV-075 (S.D. Ohio).[1]

In their motion, Plaintiffs acknowledge that Defendants have undertaken certain measures to notify class members about the potential dangers arising from their receipt of unscreened tissue. Specifically, Defendants sent information to their customers, i.e., doctors, dentists, and other health care providers, regarding the need for testing of those who received the tissue. According to Plaintiffs, Defendants' reliance on health care providers to notify patients "naturally resulted in a myriad of different letters with language vastly varying in severity and sincerity." (Defs.' Mot. at 2.) For instance, Plaintiffs contend that one notice sent by a doctor did not convey any sense of urgency surrounding the need for testing, and contained only positive statements about the unscreened tissue. (Defs.' Mot. at 3.) Therefore, Plaintiffs' ask the Court to order Defendants to provide an updated notice to the patients about the need for testing. The form of notice would be agreed upon by the parties and approved by the Court. It would advise patients that Defendant Medtronic, Inc., has offered free preliminary blood tests. It would also explain the rationale for such tests.

Plaintiffs argue that the Court possesses the authority to order this notice under its "inherent powers" and its ability to manage complex multidistrict litigation. The Court has reviewed Plaintiffs' motion and does not believe that any further briefing on this issue is necessary. After giving this matter substantial consideration, the Court finds that the issue of providing notice to unnamed class members is a decision best left to the Food and Drug Administration ("FDA"). Under the doctrine of "primary jurisdiction," when an activity is arguably subject to an administrative agency's expertise, such as the FDA, federal courts must defer to the exclusive competence of that agency. *See United States v. Western Pac. R.R. Co.*, 352 U.S. 59, 63 (1956) (noting that the doctrine of primary jurisdiction "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body."); *see also San Diego Bldgs. Trade Council v. Garmon*, 359 U.S. 236 (1959); *MCI Telecomms. Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (3d Cir. 1995); *Greate Bay Hotel & Casino v. Tose*, 34 F.3d 1227, 1230 n.5 (3d Cir. 1994). This doctrine allows a court to refer an issue to the administrative body charged with overseeing the

[1]The Judicial Panel on Multidistrict Litigation transferred this matter to be consolidated with *In re: Human Tissue Products Liability Litigation*.

issue. *White v. United* States, 989 F.2d 643, 648 (3d Cir. 1993); *Richman Bros. Records, Inc. v. U.S. Sprint Commc'ns Co.*, 953 F.2d 1431, 1435 n.3 (3d Cir. 1991). Primarily, the doctrine of primary jurisdiction "is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties." *Western Pac. R.R. Co.*, 352 U.S. at 63.

In *Bernhardt v. Pfizer, Inc.*, No. 00-4042, 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. Nov. 22, 2000), the court faced an issue similar to the one raised by Plaintiffs' motion. There, the plaintiffs filed a products liability case against Pfizer for claims arising out of their use of the antihypertensive drug doxazosin, sold under the brand name "Cardura." A National Heart, Lung and Blood Institute study concluded that doxazosin was less effective than another drug in reducing some forms of cardiovascular disease. Plaintiffs sought an order requiring Pfizer to notify Cardura users and their physicians about the study's findings. The court, though, rejected this request. Invoking the doctrine of primary jurisdiction, the court noted that "whether the notice requested by plaintiffs is warranted is a decision that has been squarely placed within the FDA's informed expert discretion." *Id.* at *9. The court, therefore, ordered the plaintiffs to seek relief before the FDA instead.

The regulations implementing the Federal Food, Drug, and Cosmetic Act vest the FDA with the authority to monitor and supervise product recall. *See* 21 C.F.R. § 7.40(a). These regulations set forth specific recall procedures whereby the FDA assumes control over monitoring recalls and assesses the adequacy of a firm's efforts in undertaking the recall. *See id.* §§ 7.40-7.59.[2] Notably, the regulations require the FDA to evaluate the precise issue requested by Plaintiffs' motion – i.e., the adequacy and extent of recall communications. *See id.* §§ 7.41-7.42. For instance, when a recall occurs, the FDA regulations provide that an ad hoc committee of scientists will perform a "health hazard evaluation" taking various factors into account. *Id.* § 7.41(a). These scientists will then reach a conclusion as to the health hazard presented by the product being recalled, and subsequently assign a classification, i.e., Class I, Class II, or Class III, to indicate the health hazard posed. *Id.* § 7.41(b). The FDA regulations also specify the factors that firms must consider when developing a recall strategy. *Id.* § 7.42(a)(1). The FDA then "review[s] the adequacy of [the] proposed recall strategy developed by a recalling firm and recommend[s] changes as appropriate." *Id.* § 7.42(a)(2). The regulations further dictate the elements to be considered in formulating a recall strategy, and specifically require the firm to assess the "depth of the recall" and the content of a public warning. *Id.* § 7.42(b)(1)-(2). Moreover, the regulations provide guidelines for the "format, content and extent" of the recall communications "commensurate with the hazard of the product being recalled." *Id.* § 7.49(a). Finally, the FDA determines when the recall will be terminated. *Id.* § 7.55(a).

As these regulations show, Congress clearly vested the FDA with the regulatory authority to assess and manage the communications regarding product recalls. Implicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is

[2]In this case, the FDA has exercised its oversight regarding the recall at issue.

required, what the notice should contain, and who the notice should be sent to. By requesting the Court to issue a similar notice here, Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA. The Court, though, does not have the expertise to undertake such a task. Therefore, as the court found in *Bernhardt*, this matter is best left to the FDA's considered competence in these matters.

In addition, the Court notes that ordering notice could create a potentially dangerous situation. An order from this Court would not preclude the FDA from issuing another notice regarding the recall, or requiring Defendants to do so. This could create the potential for inconsistent notices being sent to recipients of the unscreened tissue. The court in *Bernhardt* recognized this potential for confusion and likewise considered it a "substantial danger." *Bernhardt*, 2000 U.S. Dist. LEXIS 16963, at *9.

Accordingly, the Court will deny Plaintiffs' motion and direct Plaintiffs, should they wish, to file a "citizens' petition" with the FDA under 21 C.F.R. § 10.30. An appropriate Order accompanies this Letter Opinion.

s/William J. Martini
William J. Martini, U.S.D.J.

cc: All counsel of record via ECF.